

Tuberculosis Laboratory Cooperative Agreement: Annual Aggregate Report, 2008

INSIDE THIS REPORT:

National Workload Data	2
Ratio of Specimens per Patient	2
Time for receipt of clinical specimens	3
TAT for AFB smear microscopy	3
Positivity rate for direct detection	4
Methodology for Direct Detection	4
Methodology for ID	4
TAT for ID from clinical specimen	5
TAT for DST from clinical specimen	5
Positivity of Cultures and Isolates	6
Key Findings and Guidance	6

Inaugural Report

The Laboratory Capacity Activity in the Mycobacteriology Laboratory Branch (MLB) in the Division of Tuberculosis Elimination (DTBE) is pleased to introduce the first edition of the "Tuberculosis Laboratory Cooperative Agreement: Annual Aggregate Report". The data contained herein are a compilation of the workload and turnaround time for calendar year 2008 taken from TB Elimination Cooperative Agreement narratives by public health laboratories (PHLs) receiving support via this mechanism. These data provide an opportunity for PHLs to benchmark themselves by comparing their own laboratory data with those from peers with similar testing volumes. Benchmarking may serve as a useful guide for identifying testing practices and algorithms that are successful or need examination.

A few items must be considered when reviewing this report. First, the data are self-reported by PHLs. The interpretation of the statistic and the calculation used to derive the reported values may differ between laboratories. Second, although the same data were requested from all 58 PHL, not every PHL reported complete data. In the future, we expect that all PHLs will report data for each variable. Complete reporting is imperative for providing an accurate reflection of the work being performed over time to be described in future aggregate reports. Third, unless noted otherwise, data are reported on a "per patient" and not "per specimen" basis. Lastly, due to the limitations presented above, this report is to be used only as a guide and is not intended for other purposes that may be disciplinary in nature.

The MLB thanks you for your continued dedication and hard work in providing TB laboratory testing services. We hope that you find this report both interesting and informative. Please let us know if you have any comments, questions, or suggestions that might improve the quality of future reports.

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TABLE 1. National Workload Data for TB Elimination Cooperative Agreement Recipient Labs in 2008.

Variable	Total number	Minimum number per site	Maximum number per site	Number labs reporting
Clinical specimens received ^a	295,416	306	23,500	58
Patients for whom a clinical specimen was submitted ^b	118,914	124	10,934	58
Patients with at least one specimen culture positive for MTBC ^c	5,745	1	792	58
Patients for whom a reference isolate was submitted ^d	21,250	0	2,575	58
Patients with at least one reference isolate identified as MTBC	3,327	0	276	55
Patients for whom DST ^e for first-line drugs was performed	8,255	2	895	58
Patients for whom clinical specimen was tested directly with NAAT ^f or other rapid detection test	13,232	0	5,855	57
Patients NAAT positive for MTBC	2,479	0	567	52

^a Processed and cultured, not including isolates referred from other laboratories, ^b Processed and a TB culture inoculated,

^c *Mycobacterium tuberculosis* complex, ^d Received to rule out or confirm the identification of MTBC,

^e Drug susceptibility testing, ^f Nucleic acid amplification test

Ratio of Total Number of Specimens to Number of Patients Tested (N=58)

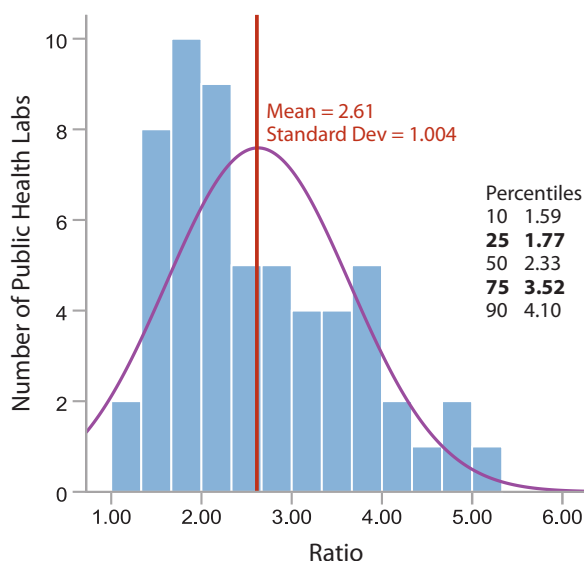


Figure 1.

Ratio of total specimens tested to number of patients tested. The mean number of specimens cultured per patient was 2.61. In general, laboratories in high-incidence areas have a higher ratio and labs located in lower-incidence areas have a lower ratio. A value far in excess of the 10th and 90th percentiles (<1.59 or >4.10 specimens cultured per patient) may suggest that a review of laboratory policies is indicated.

Percent of Specimens Received Within 1, 2, and 3 Days After Collection

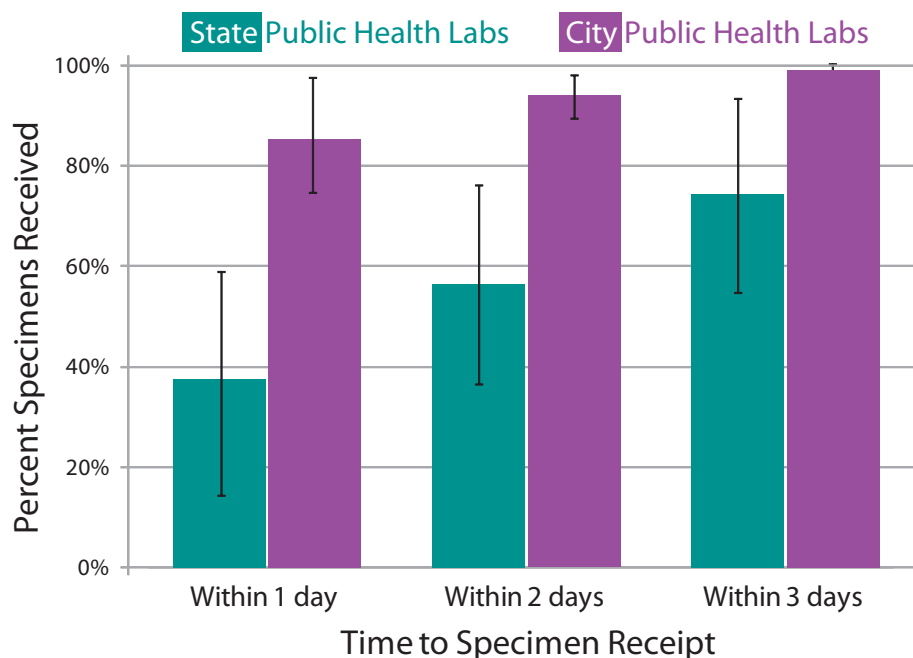


Figure 2.

The current goal of laboratory receipt of specimens within 1 day of collection was achieved on average 37% of the time in state public health labs. Barriers described in cooperative agreement narratives included lack of a courier system, difficult terrain, remote locales, and limited education to providers. In addition, receipt of specimens can be affected by weekends and furlough days.

AFB Smear Results Reported Within One Day

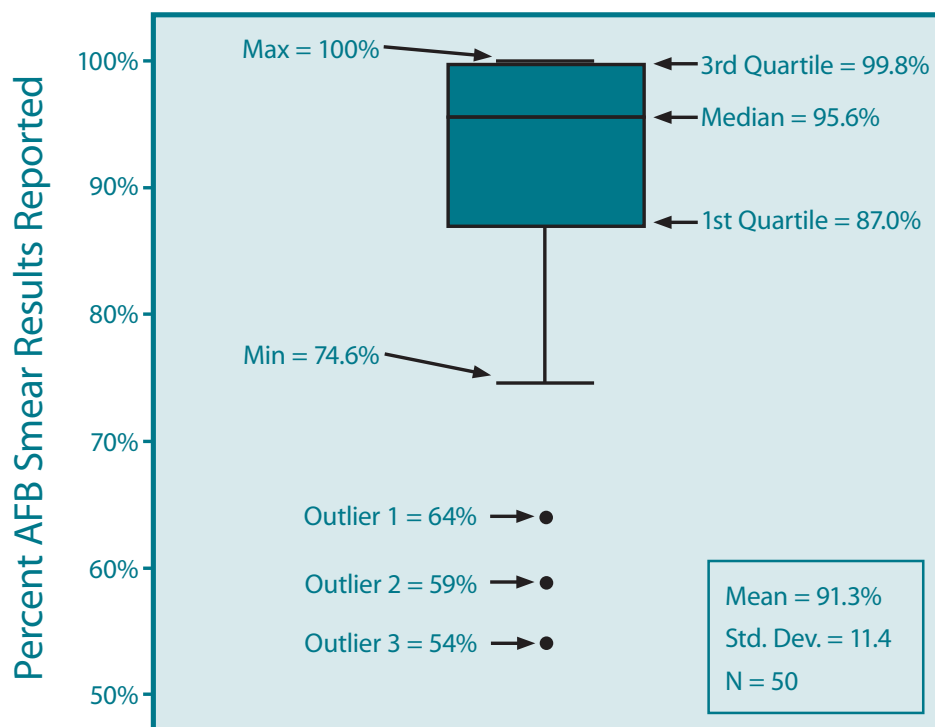


Figure 3.

Box plot display of the percent of AFB smear results reported within one day of specimen receipt. An overwhelming majority of cooperative agreement recipient labs reported 87% or more of AFB smear results within 1 day of specimen receipt. Three laboratories reported values that were statistically below the observed minimum for other sites. Outliers should assess potential reasons for difficulty in meeting this objective.

Positivity of Direct Detection Stratified by Testing Volume (N = 39 labs)

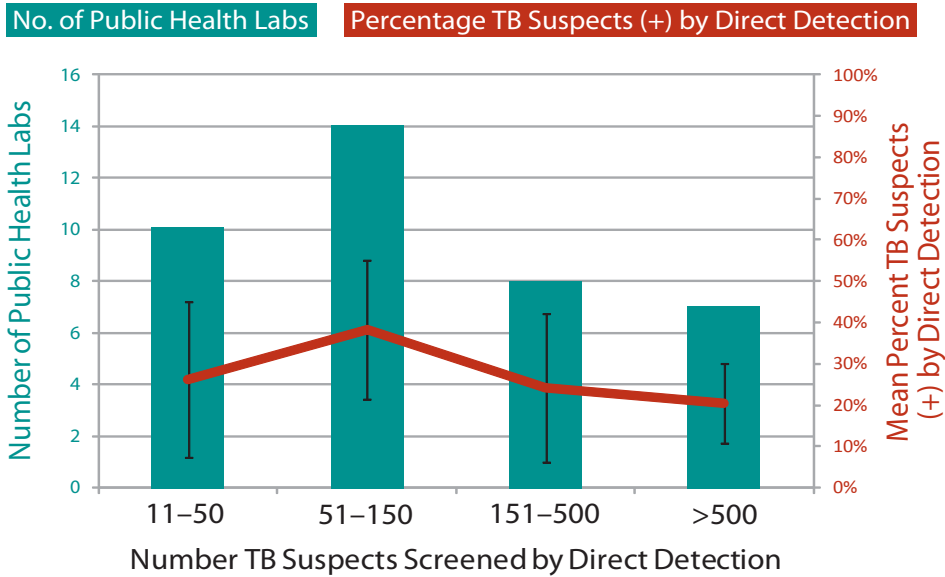


Figure 4. Overall, approximately 19% of TB suspects with a clinical specimen tested by a direct detection method were positive for MTBC. The positivity rate declined with an increasing number of TB suspects examined. PHL should work with submitters and their TB Control Program to determine an appropriate testing algorithm for utilization of direct detection methodologies.

Rapid Direct Detection Methods (N = 58)

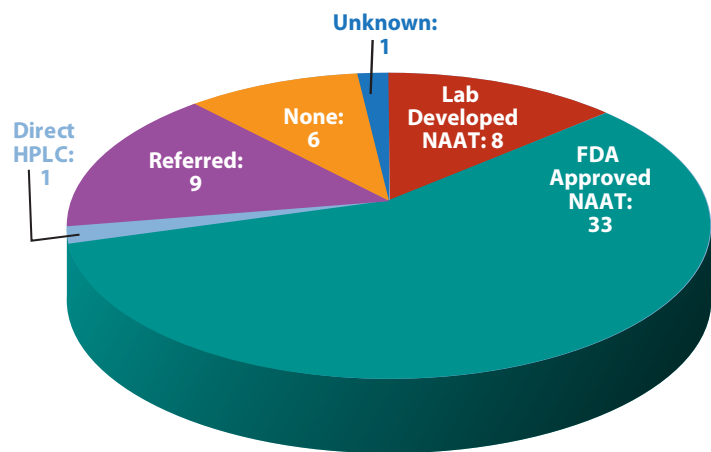


Figure 5. Methods used by public health laboratories for rapid direct detection of MTBC from clinical specimens.

ID from Culture, Primary Methods (N = 58)

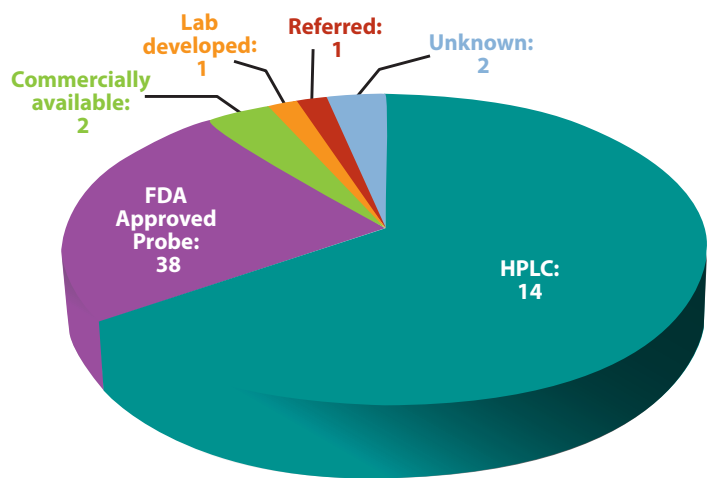


Figure 6. Primary methods used by public health laboratories for identification of MTBC from culture.

Percent ID Reported Within 21 Days of Specimen Receipt Stratified by Testing Volume (N=49)

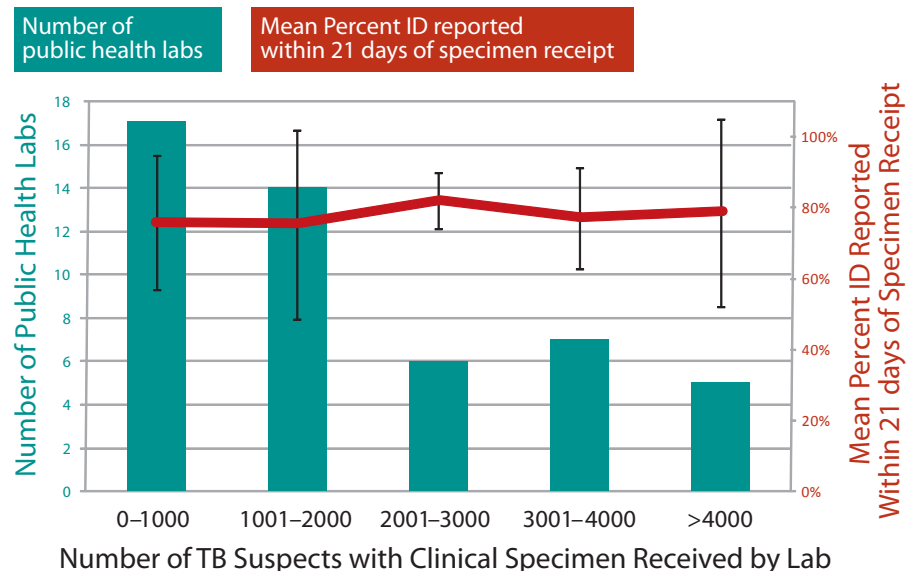


Figure 7.

Many PHLs are near to or exceeding 80% of MTBC identifications being reported within 21 days of specimen receipt by the laboratory. There were no significant differences in turnaround time based on volume of testing. Some PHLs challenged in meeting this goal reported issues with staffing that limit the number of times ID assays can be performed each week.

Percent First-line DST Reported Within 28 Days of Specimen Receipt Stratified by Testing Volume (N=51)

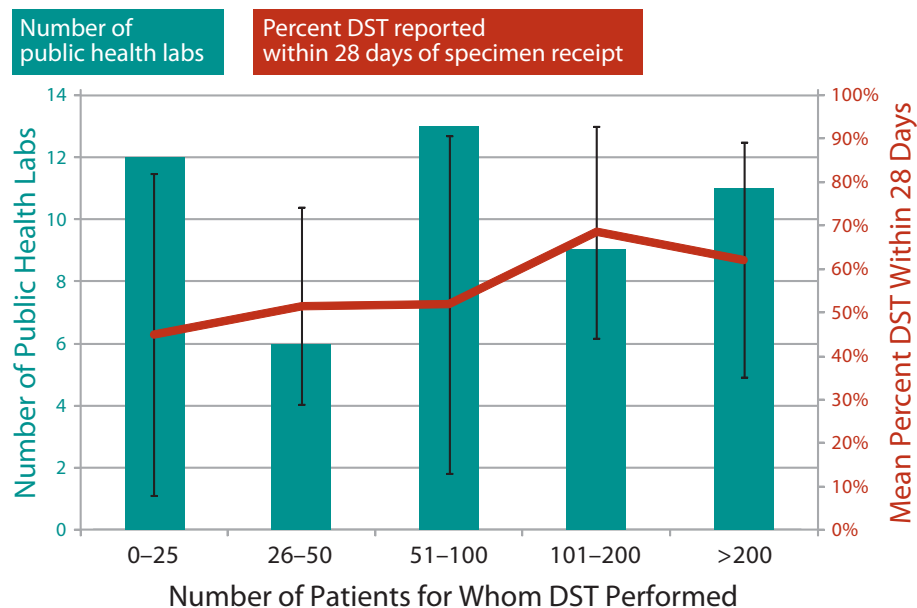


Figure 8.

Overall, 55% of first-line DST results are reported within the recommended 28 days of specimen receipt in the laboratory. In general, PHLs that performed more DST per year reported a higher percentage of results within 28 days. Barriers to meeting recommended TAT should be evaluated to ensure progress of reporting DST results within 28 days of receipt.

Positivity of Cultures Stratified by Volume of Patient Specimens Tested

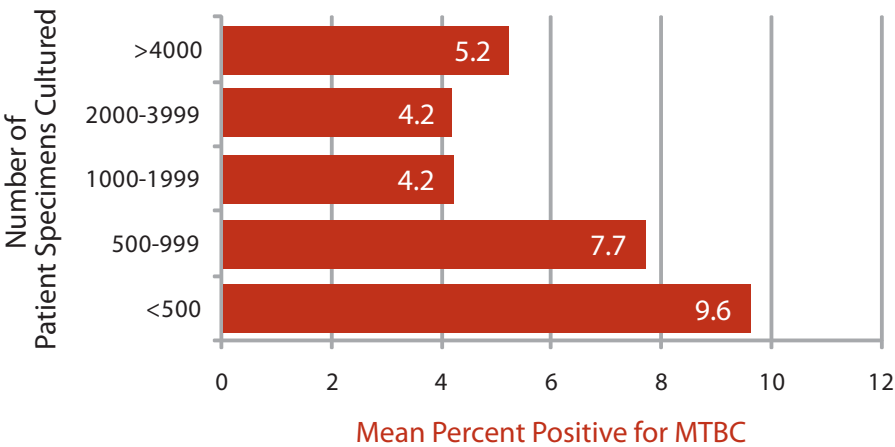


Figure 9.
This figure represents the percent of cultures positive for MTBC stratified by volume of patients tested (not volume of total specimens). Overall, positivity declined with increasing volume, except for labs testing very high numbers; however the differences among volumes were not statistically significant ($p = .099$, Anova test, SPSS, v. 17).

Positivity of Isolates Stratified by Volume of Patient Isolates Tested

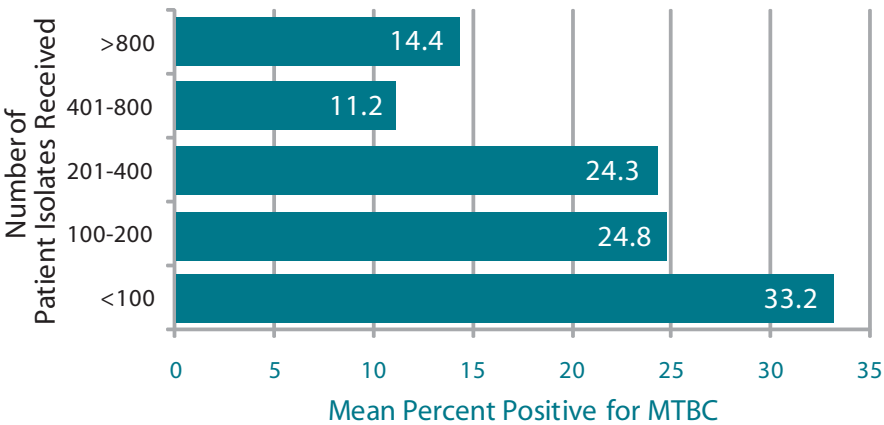


Figure 10.
This figure represents the percent of reference isolates, positive for MTBC, stratified by volume of patients tested. Similar to Figure 9, positivity declined with increasing volume, except for labs testing very high numbers; however the differences among volumes were not statistically significant ($p = 0.25$, Anova test, SPSS, v. 17).

Monitoring the positivity of cultures and isolates over time (i.e., recovery rate of MTBC), is a useful performance indicator for the laboratory.

Summary of Key Findings:

1. Overall, PHLs are meeting the recommended TAT for reporting of smear results in one day, and for identification of MTBC within 21 days of specimen receipt. However, meeting the CDC recommended TAT of specimen receipt within one calendar day of collection and the provision of first-line DST results within 28 days of specimen receipt remain significant challenges.
2. Due to reporting variability by PHLs, it is difficult to determine the percent of patients meeting the Healthy People 2010 Goal of reducing the average time for a laboratory to confirm and report TB cases (Target: 2 days for 75 percent of cases that are later culture confirmed). However, it is evident that PHLs have great difficulty meeting this goal. PHLs should continue to ensure access to direct detection methodologies (e.g., nucleic acid amplification tests) for rapid identification of MTBC from clinical specimens.
3. PHL Cooperative Agreement narratives provide insight into existing barriers for meeting TAT goals. For example, large geographical areas, inadequacies in postal delivery methods, lack of state-sponsored courier systems, and the practice of batching specimens all contribute to difficulties for timely specimen delivery. Additionally, staffing and scheduling issues, lab practices such as the need to wait for growth on solid media, and policies that delay reporting of preliminary results have all been identified as contributing to lengthy TAT for DST.
4. Analyzing both aggregate and individual PHL data may help to identify trends and patterns that inform strategies to reduce barriers. These data are useful for advocacy of policy changes and reveal opportunities for operational research. Data analysis aids in assessment of both national recommendations as well as your own PHL performance objectives to ensure they closely reflect goals that are realistic and tied to measurable outcomes.